

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA-2020-0016]

Meetings to Implement Pandemic Response Voluntary Agreement under Section
708 of the Defense Production Act

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Announcement of meetings.

SUMMARY: The Federal Emergency Management Agency (FEMA) is holding meetings under the Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Medical Devices to Respond to COVID-19 and the Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Drug Products, Drug Substances, and Associated Medical Devices to Respond to COVID-19, in order to implement the Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic.

DATES:

- Thursday, March 24, 2022, from 1 p.m. to 3 p.m. Eastern Time (ET).
- Thursday, April 7, 2022, from 1 p.m. to 3 p.m. ET.

FOR FURTHER INFORMATION CONTACT: Robert Glenn, FEMA Office of Response and Recovery's Office of Business, Industry, and Infrastructure Integration, via email at *OB3I@fema.dhs.gov* or via phone at (202) 212-1666.

SUPPLEMENTARY INFORMATION: Notice of these meetings is provided as required by section 708(h)(8) of the Defense Production Act (DPA), 50 U.S.C. 4558(h)(8), and consistent with 44 CFR part 332.

The DPA authorizes the making of "voluntary agreements and plans of action" with representatives of industry, business, and other interests to help provide for the national defense.¹ The President's authority to facilitate voluntary agreements with respect to responding to the spread of COVID-19 within the United States was delegated to the Secretary of Homeland Security in Executive Order 13911.² The Secretary of Homeland Security further delegated this authority to the FEMA Administrator.³

On August 17, 2020, after the appropriate consultations with the Attorney General and the Chairman of the Federal Trade Commission, FEMA completed and published in the *Federal Register* a "Voluntary Agreement, Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic" (Voluntary Agreement).⁴ Unless terminated earlier, the Voluntary Agreement is effective until August 17, 2025, and may be extended subject to additional approval by the Attorney General after consultation with the Chairman of the Federal Trade Commission. The Agreement may be used to prepare for or respond to any pandemic, including COVID-19, during that time.

On May 24, 2021, four additional plans of action under the Voluntary Agreement

– the Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and

Distribution of Diagnostic Test Kits and other Testing Components to respond to

COVID-19, the Plan of Action to Establish a National Strategy for the Manufacture,

Allocation, and Distribution of Drug Products, Drug Substances, and Associated Medical

Devices to respond to COVID-19, the Plan of Action to Establish a National Strategy for

the Manufacture, Allocation, and Distribution of Medical Devices to respond to COVID-

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¹ 50 U.S.C. 4558(c)(1).

² 85 FR 18403 (Apr. 1, 2020).

³ DHS Delegation 09052, Rev. 00.1 (Apr. 1, 2020); DHS Delegation Number 09052 Rev. 00 (Jan. 3, 2017).

⁴ 85 FR 50035 (Aug. 17, 2020). The Attorney General, in consultation with the Chairman of the Federal Trade Commission, made the required finding that the purpose of the voluntary agreement may not reasonably be achieved through an agreement having less anticompetitive effects or without any voluntary agreement and published the finding in the *Federal Register* on the same day. 85 FR 50049 (Aug. 17, 2020).

19, and the Plan of Action to Establish a National Strategy for the Manufacture,
Allocation, and Distribution of Medical Gases to respond to COVID-19 – were finalized.⁵
These plans of action established several sub-committees under the Voluntary
Agreement, focusing on different aspects of each plan of action.

On October 15, 2021, the sixth plan of action under the Voluntary Agreement – the Plan of Action to Establish a National Strategy for the Coordination of National Multimodal Healthcare Supply Chains to Respond to COVID-19 – was finalized.⁶ This plan of action established several sub-committees under the Voluntary Agreement, focusing on different transportation categories.

The meetings are chaired by the FEMA Administrator's delegates from the Office of Response and Recovery (ORR) and Office of Policy and Program Analysis (OPPA), attended by the Attorney General's delegates from the U.S. Department of Justice, and attended by the Chairman of the Federal Trade Commission's delegates. In implementing the Voluntary Agreement, FEMA adheres to all procedural requirements of 50 U.S.C. 4558 and 44 CFR part 332.

Meeting Objectives: The objectives of the meetings are as follows:

- Convene the Requirements Sub-Committees under the Medical Devices and Drug Products/Drug Substances Plans of Action to establish priorities related to the COVID-19 response under the Voluntary Agreement.
- 2. Gather Requirements Sub-Committee Participants and Attendees to ask targeted questions for situational awareness.
- Identify pandemic-related information gaps and areas that merit sharing by holding quarterly meetings of the Requirements Sub-Committees with key stakeholders.

⁵ See 86 FR 27894 (May 24, 2021). See also 86 FR 28851 (May 28, 2021).

⁶ See 86 FR 57444 (Oct. 15, 2021). See also 87 FR 6880 (Feb. 7, 2022).

4. Identify potential Objectives and Actions that should be completed under the Requirements Sub-Committees.

Meetings Closed to the Public: By default, the DPA requires meetings held to implement a voluntary agreement or plan of action be open to the public.⁷ However, attendance may be limited if the Sponsor⁸ of the Voluntary Agreement finds that the matter to be discussed at a meeting falls within the purview of matters described in 5 U.S.C. 552b(c), such as trade secrets and commercial or financial information.

The Sponsor of the Voluntary Agreement, the FEMA Administrator, found that these meetings to implement the Voluntary Agreement involve matters which fall within the purview of matters described in 5 U.S.C. 552b(c) and the meetings are therefore closed to the public.

Specifically, these meetings may require participants to disclose trade secrets or commercial or financial information that is privileged or confidential. Disclosure of such information allows for meetings to be closed to the public pursuant to 5 U.S.C. 552b(c)(4).

The success of the Voluntary Agreement depends wholly on the willing participation of the private sector participants. Failure to close these meetings to the public could reduce active participation by the signatories due to a perceived risk that sensitive company information could be released to the public. A public disclosure of a private sector participant's information executed prematurely could reduce trust and support for the Voluntary Agreement.

A resulting loss of support by the participants for the Voluntary Agreement would significantly hinder the implementation of the Agency's objectives. Thus, these meeting closures are permitted pursuant to 5 U.S.C. 552b(c)(9)(B).

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⁷ See 50 U.S.C. 4558(h)(7).

⁸ "[T]he individual designated by the President in subsection (c)(2) [of section 708 of the DPA] to administer the voluntary agreement, or plan of action." 50 U.S.C. 4558(h)(7).

Deanne Criswell,

Administrator,

Federal Emergency Management Agency.

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